PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	12.06.2006

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
414/04493	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2005/000442	28.04.2005	29.04.2004

Applicant
REABILITY INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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18 JUN 2006
To: MF MK OK
FENSTER & Co.

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Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 414/04493	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IL2005/000442	International filing date *(day/month/year)* 28.04.2005	Priority date *(day/month/year)* 29.04.2004
International Patent Classification (IPC) or national classification and IPC INV. A61N1/36 A61B5/11 A61B5/0488 A61H1/02		
Applicant REABILITY INC. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28.02.2006	12.06.2006

Name and mailing address of the international preliminary examining authority:	Authorized officer
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL2005/000442

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-32 as originally filed

   Claims, Numbers

   1-31 filed with telefax on 28.02.2006

   Drawings, Sheets

   1/7-7/7 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 31

because:

☒ the said international application, or the said claims Nos. 31 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*.

☒ no international search report has been established for the said claims Nos. 31

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-7,11-13,15-18,20,26,27,29
Inventive step (IS)	Yes:	Claims	
	No:	Claims	8-10,14,19,21-25,28,30
Industrial applicability (IA)	Yes:	Claims	1-30
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III.

No search has ben carried out (Rule 39.1(iv) PCT) for claim 31, since it relates to a method for treatment of the human or animal body by therapy. Indeed, claim 31 pertains to the delivery of a therapeutic neuromuscular stimulation signal to the human body. Consequently, no opinion will be formulated with respect to the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V.

1. Reference is made to the following documents:
   D1 : WO 02/092164 A (FONDATION SUISSE POUR LES CYBERTHESES; BRODARD, ROLAND; CLAVEL, REYMON) 21 November 2002
   D2 : US 5 466 213 A (HOGAN ET AL) 14 November 1995
   D3 : US 4 499 900 A (PETROFSKY ET AL) 19 February 1985
   D4 : US 4 724 842 A (CHARTERS ET AL) 16 February 1988

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

2.1 Preliminary remark

It is pointed out that the features of the "mechanical motion element **coupled to at least one of said body portion and a mirror body portion**" and the "EMG sensor **coupled to said mirror body portion**" only indicates the suitability of the respective parts of the apparatus to be coupled to the body: in fact, they rather define the use of the apparatus rather than clearly defining the apparatus in terms of its technical features. The features emphasised in bold do therefore not limit the scope of claim 1 (Article 6 PCT).

2.2 Document **D1** (see in particular figs. 1-4) discloses (the references in parentheses applying to this document) an apparatus for muscle activation comprising:
- at least one electrode (37, 38) adapted to deliver a neuromuscular stimulation signal to a body portion;

- at least one controller (31) adapted to provide a NMES signal comprising a sequence of stimulation signals to said at least one electrode; and
- a mechanical motion element (2, 3, 4, 6, 7, 8, 20, 21, 22) suitable (adapted) to be coupled to at least one of said body portion and a mirror body portion,
- wherein said mechanical motion element is operatively coupled to said at least one controller (see fig. 4) and wherein said at least one controller controls said NMES signal in conjunction with said mechanical motion element (p. 12, 2nd paragraph and p. 21, second and third paragraphs).

Further, as becomes apparent from p. 19, l. 13-15 and l. 30-32, a feedback control based on the muscular activity controller is implemented in the controller of D1: indeed, D1 discloses the use of muscular model established by analysing the EMG signal of a mirror body portion (see p. 19, l. 30-32). **Hence, at least one EMG sensor is disclosed by D1 and the EMG sensor is certainly adapted to be coupled to a mirror body portion**.
D1 clearly discloses the "double feedback" as claimed in claim 1 (i.e. mechanical motion feedback and EMG feedback) (see p. 21, l. 15-28: Closed-Loop Electrical Muscle Stimulation).

Accordingly, all the features of claim 1 are anticipated by D1 and claim 1 therefore lacks novelty (Article 33 (2) PCT).

2.3 Further, **D2** (see in particular col. 3, l. 3-7; col. 6, l. 54-59; fig. 14) also anticipates the subject-matter of claim 1, since it discloses an apparatus for muscle activation comprising:
- at least one electrode (E1 or E2) adapted to deliver a neuromuscular stimulation signal to a body portion;
- at least one controller (AB, 32) adapted to provide a NMES signal comprising a sequence of stimulation signals to said at least one electrode; and
- a mechanical motion element (10) suitable to be coupled to at least one of said body portion and a mirror body portion,
- wherein said mechanical motion element is operatively coupled to said at least one controller and wherein said at least one controller controls said NMES signal in conjunction with said mechanical motion element (col. 6, l. 54-59).

D2 (col. 3, l. 3-7) discloses also an EMG sensor used in combination with an NMES stimulator ("Electromyographic implementation feature **and** a Functional Electric Stimulation implementation feature).

3. Dependent claims 2-30 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

3.1 **D1** anticipates the subject-matter of following claims (Article 33 (2) PCT):

- Claims 1-5: in D1, the mechanical motion element moves, guides and measures motion of the body portion (first leg) and the mirror body portion (second leg), which motion is in response to said NMES sequence.
- Claim 6: the controller of D1 is programmable, so a programmer is implicitly disclosed in D1.
- Claim 7: in D1, a closed loop feedback control for booth the mechanical motion and the EMG controlled stimulation is effected: hence a sequence optimisation is also disclosed.
- Claims 11-13: see D1, p. 21, second and third paragraphs.
- Claim 15: see memory (39) of D1.
- Claims 16-18: in D1, the operator can modify the stimulation sequence as desired (see p. 19, 4th paragraph - p. 20, 3rd paragraph).
- Claim 20: force sensor (35) in D1.
- Claim 26: in D1, one can choose from stimulation only, stimulation assisted rehabilitation and "mechanical" rehabilitation only (see p. 21, last paragraph - p. 23, 3rd paragraph): therefore, the controller can act independently of the mechanical motion element.
- Claim 27: in D1, the electrodes are placed on the thighs and on the legs (see fig. 4), hence the NMES sequence is for application to at least two muscles.
- Claim 29: mechanical motion elements (2, 3, 4) and motors (20, 21, 22) of D1 represent a robotic actuator (see also p. 15, l. 2).

3.2 The features of claims 8-10, 14, 19, 21-25, 28 and 30 represent slight constructional changes from the known devices (see documents **D1-D4**) which come within the scope of the customary practice followed by persons skilled in the art, especially as the

advantages thus achieved can readily be foreseen. Moreover, these features concern straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to improve the known devices. Consequently, the subject-matter of these claims lacks an inventive step (Article 33 (3) PCT.

Re Item VI.

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 2004/050172	17.06.2004	03.12.2003	04.12.2003

This document could become relevant for novelty in further proceedings before the EPO.

Re Item VII.

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

CLAIMS

1. Apparatus for muscle activation, comprising:

at least one electrode (138) adapted to deliver a neuromuscular stimulation (NMES) signal to a body portion (146);

at least one controller (124) adapted to provide a NMES signal comprising a sequence of stimulation signals to said at least one electrode (138);

a mechanical motion element (300) coupled to at least one of said body portion (146) and a mirror body portion (102), wherein said mechanical motion element (300) is operatively coupled to said at least one controller (124) and wherein said at least one controller (124) controls said NMES signal in conjunction with said mechanical motion element (300); and,

at least one EMG sensor (104) coupled to said mirror body portion (102), wherein said controller (124) is adapted to generate said NMES signal based on sensed EMG signals from said at least one EMG sensor (104).

2. Apparatus according to claim 1, wherein said mechanical motion element (300) moves said body portion (146).

3. Apparatus according to claim 1 or claim 2, wherein said mechanical motion element (300) measures motion of said body portion (146), which motion is in response to said NMES sequence.

4. Apparatus according to any of the preceding claims, wherein said mechanical motion element (300) guides motion of said body portion (146), which motion is in response to said NMES sequence.

5. Apparatus according to any of the preceding claims, wherein said mechanical motion element (300) guides motion of said mirror body portion (102), which NMES is generated in response to said motion.

6. Apparatus according to any of the preceding claims, comprising a programmer adapted to program NMES sequences for said electrodes (138).

7. Apparatus according to claim 6, wherein said programmer includes a sequence optimizer which modifies NMES sequences in response to at least one optimization criterion.

8. Apparatus according to claim 7, wherein said optimization criterion comprises the ability of a patient.

9. Apparatus according to claim 7, wherein said optimization criterion comprises electrode limitations.

10. Apparatus according to claim 7, wherein said optimization criterion comprises a quality of result, as measured by said mechanical motion element (300).

11. Apparatus according to claim 1, further comprising at least one EMG sensor coupled to a mirror body portion (102) on a different person for measuring EMG signals from the different person.

12. Apparatus according to claim 1, further comprising at least one EMG sensor (148) coupled to said body portion (142) for measuring EMG signals from the body portion (142).

13. Apparatus according to claim 12, wherein said controller (124) generates a NMES signal responsive to at least one of an amplitude and existence of EMG signal at a location to which NMES is to be applied.

14. Apparatus according to any of the preceding claims, wherein said controller (124) is adapted to generate an indication of which electrodes of said at least one electrode to use.

15. Apparatus according to any of the preceding claims, comprising a memory storing therein a plurality of NMES sequences, for at least one daily activity.

16. Apparatus according to any of the preceding claims, comprising a user input for generating a NMES sequence.

17. Apparatus according to any of the preceding claims, wherein said controller (124) is adapted to generate a NMES sequence for use for said electrodes based on a desired motion of said body portion (146).

18. Apparatus according to any of the preceding claims, wherein said controller (124) is adapted to modify a stored NMES sequence for use for said electrodes based on a desired motion of said body portion (146).

19. Apparatus according to any of the preceding claims, wherein said controller (124) is adapted to compare an actual effect of a NMES sequence and a desired effect of said sequence and detect at least one deviation.

20. Apparatus according to any of the preceding claims, wherein said mechanical motion element (300) is adapted to measure force applied by said body portion (146) in response to said NMES.

21. Apparatus according to any of the preceding claims, comprising a calibrator adapted to calibrate at least one sensor associated with motion of said portion.

22. Apparatus according to any of the preceding claims, comprising an interactive user guide for electrode NMES programming.

23. Apparatus according to any of the preceding claims, wherein said electrodes are implantable.

24. Apparatus according to any of the preceding claims, wherein said electrodes form part of a prosthesis.

25. Apparatus according to any of the preceding claims, wherein said electrodes are adapted to be worn for the long term.

26. Apparatus according to any of the preceding claims, wherein said electrodes and at least one of said at least one controller (124) are adapted to act independently of and removed from said mechanical motion element (300).

27. Apparatus according to any of the preceding claims, wherein said NMES sequence comprises a sequence for application to at least two muscles.

28. Apparatus according to any of the preceding claims, wherein said NMES sequence is at least 20 seconds long,

29. Apparatus according to any of claims wherein said mechanical motion element (300) comprises an actuator.

30. Apparatus according to claim 29, wherein said actuator comprises a robotic actuator with at least 3 degrees of motion.

31. A method of electrode setting for NMES, comprising:

applying a NMES sequence to a limb (146);

measuring motion of the limb (146);

modifying said NMES sequence responsive to said measured motion; and

repeating said applying, said measuring and said modifying, using a mechanical motion element (300) to at least one of move said limb (146), resist motion of said limb (146) and measure motion of said limb (146).